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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,211	02/10/2005	Kaoru Usui	050053	6407
23850 7590 07/17/2008 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005				
EXAMINER				
YAGER, JAMES C				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,211

Applicant(s)

USUI ET AL.

Examiner

JAMES YAGER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed 02 May 2008 has been entered. Claims 1-5 are pending in the application.
2. The rejections of claims 1-5 under 35 USC §112 second paragraph are withdrawn in light of the amendments to the claims.

Claim Objections

3. Claims 1-5 are objected to because of the following informalities: Claim 1 recites "...a adhesive portion formed by comprising, as a main component..." The phrase "formed by comprising" is not clear. The claim language could be clarified by replacing "formed by comprising" with "comprising".

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (US 5,046,479) in view of Munro (US 2002/0037270).

Regarding claims 1, 2 and 5, Usui discloses a heat-generating body, comprising a heat-generating portion formed by sealing a heat-generating composition causing an exothermic reaction in the presence of air (col 2, ln 23-35) in an air-permeable container in desired form such as bag form or sheet form (col 2, ln 35-36) and an adhesive portion (col 2, ln 35-40) to enable the heat-generating body to be attached to skin (col 1, ln 10-11).

Usui does not disclose the adhesive portion comprising, as a main component, a water-containing hydrophilic gel agent obtained from a hydrophilic polymeric thickening agent, wherein an organic filling agent is added in the water-containing hydrophilic gel agent in the adhesive portion.

Munro discloses a body for attaching to skin ([0004]) comprising an improved adhesive portion formed by comprising, as a main component, a water-containing hydrophilic gel agent obtained from a hydrophilic polymeric thickening agent (see

[0050]-[0054], which discloses that hydrogels based on interpenetrating polymer networks (IPN) are defined as a combination of two polymers, for example monomer 1 polymerized and crosslinked to give a polymer which is then swollen with monomer 2. Suitable water soluble polymers for the formation of semi-IPN's include polyvinyl alcohol). Munro also discloses that the adhesive possesses superior adhesion characteristics ([0004]) and is more resistant to bacteria and molds ([0007]). Additionally, Munro discloses said adhesive comprising an organic filling agent in the water containing hydrophilic gel agent in the adhesive portion ([0039], citric acid).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the hydrogel adhesive disclosed by Munro as the adhesive in the heat-generating body of Usui, since Munro's hydrogel adhesive possesses superior adhesive and microorganism resistant qualities since Usui is in the same field of endeavor as Munro et al. (adhering an apparatus to the skin of a person).

While modified Usui does not disclose the critical moisture value of the adhesive portion to be plus or minus 2% of the critical moisture value of the heat generating portion, said critical moisture value of the adhesive portion does not confer patentability to the claim. The examiner notes that, even though modified Usui does not disclose the critical moisture value of the heat-generating portion, the heat-generating portion of Usui will inherently have a critical moisture value. Therefore, since the instant specification is silent to unexpected results, and because the adhesiveness and microbial resistance of the adhesive portion are variables that can be modified by adjusting the water activity (critical moisture value) of the adhesive portion (see Munro, [0004] and [0007]) the

precise critical moisture value of the adhesive portion would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed critical moisture value of the adhesive portion cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the critical moisture value of the adhesive portion in modified Usui to obtain the desired critical moisture value (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223). Said optimum critical moisture values of the adhesive portion include values allowing the difference between the critical moisture value of the adhesive and the critical moisture value of the heat-generating portion to be 2% or less.

7. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (US 5,046,479) in view of Munro (US 2002/0037270) as applied to claims 1 and 2 above, and further in view of Otsuka et al. (US 2001/0010847).

Regarding claims 3 and 4, modified Usui discloses all the claim limitations as set forth above. Usui further discloses that the heat-generating body is contained in an air-tight container bag (col 1, In 16-20, wrapped, hermetically sealed bag). Additionally, Usui discloses that the adhesive portion is attached to the heat-generating portion (col 2, In 32-37), but does not explicitly disclose how they are attached. Otsuka discloses a heat-generating body comprising a heat-generating portion and an adhesive portion

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([0050]) wherein the adhesive portion is laminated on the heat generating portion ([0061]-[0062], stacked laminate).

As Usui is not limited to any specific examples of attachment and as laminating adhesives to heat-generating bodies is well known in the art at the time the invention was made, as evidenced by Otsuka, and further, as the instant specification is silent to unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to laminate the adhesive onto the heat-generating portion as in the heat-generating body of Otsuka. Said combination would amount to use of a known attachment method for its intended use in a known environment to accomplish entirely expected result.

Response to Arguments

8. Applicant's arguments filed 02 May 2008 have been fully considered but they are not persuasive. Applicant argues:

In support of the above assertion as to the Usui and Munro et al patent publications not teaching the presently claimed invention including the important feature of a difference between critical moisture values of the heat-generating portion and the adhesive portion is 2% or less, attention is directed to the attached Declaration under 37 CFR § 1.132 of Mr. Yukio URUME, one of the inventors in the subject application. The Declaration sets forth measurements made under the supervision and control of Mr. Urume regarding the formulations according to the Usui and Munro et al patent publications.

More particularly, as is apparent from the Declaration, the critical moisture value of the adhesive of formulation 5c in the Example 5 of the Munro et al patent publication was 68%. In addition, the critical moisture values of formulations 6a and 6c in the Example 6 of the same patent were 56% and 54%, respectively.

Generally, the critical moisture value of a conventional heat-generating portion is 80% to 95%, i.e., 80% or higher. Therefore, even if the adhesive in the Munro et al publication was substituted in the heat generating device of the Usui patent, the difference between the critical moisture values is as high as "12% or higher." Consequently, the

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presently claimed invention having the difference between the critical moisture values of 2% or less is not taught or suggested by the patent publications to Usui and Munro et al.

It is therefore submitted that the conclusion contained in the Action which was used as a basis for conclusion of obviousness that one of ordinary skill in the art "would have optimized, by routine experimentation, the critical moisture value of the adhesive portion" in the modified heat-generating body according to the Usui patent "to obtain the desired critical moisture value" is inaccurate. While it appears that the adhesive portion according to the Usui patent may inherently have a moisture value, neither publication teaches a difference between critical moisture values of 2% or less

Applicant's argument is unpersuasive because applicant has not presented any evidence that the difference between the critical moisture values of the heat generating portion and the adhesive portion of modified Usui is not 2% or less.

Regarding the Declaration under 37 CFR § 1.132 of Mr. Yukio Urume dated 02 May 2008, the declaration does not set forth the critical moisture value of the heat generating portion disclosed by Usui and there is no calculation of the difference between the critical moisture values of the heat generating portion disclosed by Usui and the adhesive portion disclosed by Munro. Additionally, it is noted that the composition of Usui is different than the compositions set forth in Table 1 of the applicant's specification. For example, Usui's composition comprises water in amount from 18-20%, while the examples given in Table 1 of the instant specification comprise water in the amount of 30%. Clearly, these differences in composition will result in differences in the critical moisture values between the heat generating portion of Usui and the heat generating portion of the instant application. Applicants mere assertion that the critical moisture values of conventional heat generating portions are 80% or higher is not sufficient evidence to support an assertion that the heat generating portion of Usui in fact has a critical moisture value of 80% or more. Further, the declaration only sets forth data for three of Munro's examples. There is no evidence that the critical

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moisture values calculated for examples 5c, 6a and 6c are representative of all of the compositions disclosed by Munro given the different amounts and types of components used in the examples of Munro. It is not clear what the critical moisture values are for the other examples of Munro and if they would be closer to the critical moisture values of the heat generating portion. Therefore, the declaration does not provide persuasive evidence regarding the difference between the critical moisture values of the heat generating portion and the adhesive portion of modified Usui.

9. Applicant's arguments filed 02 May 2008 have been fully considered but they are not persuasive. Applicant argues:

It is considered improper to assert that one of ordinary skill would achieve the recited difference between the critical moisture values of 2% or less without such a teaching, since it is submitted that the teaching deficiency has been supplied using a prohibited hindsight reconstruction from applicants' own disclosure that the difference between the critical moisture values is 2% or less.

Applicants argument is unpersuasive because the rejection is not based on hindsight reconstruction, but on the fact that it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the critical moisture values based on the fact that Munro notes that water activity has an effect on the adhesiveness and microbial resistance.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES YAGER whose telephone number is (571)270-3880. The examiner can normally be reached on Mon - Thurs, 7:30am-5pm, EST, Alt. Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JY 7/10/08

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794